REMARKS

I. Status and Disposition of the Claims

As an initial matter, Applicants note that with the exception of changing the word "alloying" to "treating," this amendment is the same as the previously filed After Final Amendment not entered by the Examiner. Prior to this amendment, claims 7, 10, and 20-26 were pending. By this amendment, claim 7 has been amended to incorporate the easily diffusable elements recited by previous claim 10, with the exception of carbon. Thus, claim 10 has been cancelled.

Applicants have further amended claim 7 to recite that the "second set of properties . . . have been altered from the first set of properties by treating (rather than "alloying") the second section with an easily diffusable element." Support for this amendment can be found through the specification, particularly at page 10, lines 10-20 in the as-filed specification. This amendment was made to more accurately define the process as one of treating with a diffusable element, rather than alloying with the same elements.

In addition, Claims 20 and 21 have been amended so as to depend from a pending claim. Support for the amendment can be found in the original specification and claims.

No new matter has been introduced.

The following remarks is directed toward the final Office Action of November 1, 2006 ("Office Action"). Applicants acknowledge, with appreciation, the Examiner's withdrawal of the prior rejection of claims 7, 10, and 20-26 under 35 U.S.C. §112, second paragraph. However, the Examiner continues to reject claims 7, 10 and 22-26

under 35 U.S.C. §102(b) as alleged anticipated by Japanese Patent Application Publication No. JP 04 187159 ("Yamauchi"). Office Action, page 2. In addition, the Examiner rejects claims 7, 10 and 22-26 under 35 U.S.C. §102(e) as being allegedly anticipated by U.S. Patent No. 6,325,766 ("Anderson"). *Id.* at 2-3. Finally, the Examiner rejects claims 7, 10, 20, 21, 23 and 24 under 35 U.S.C. §103(a) as being allegedly unpatentable over Anderson in view of U.S. Patent No. 5,722,981 ("Stevens"). Applicants respectfully disagree with and traverse each of these rejections for at least the following reasons.

II. Response to Rejections

A. The §102(b) rejection of claims 7, 10 and 20-26 in view of Yamauchi is improper

The Examiner maintains that Yamauchi anticipates each and every element of claims 7, 10 and 22-26. Office Action, page 2. Applicants respectfully disagree with and traverse this rejection for at least the following reasons. However, in order to advance prosecution, Applicants have amended claim 7 so as to incorporate the easily diffusable elements of previous claim 10, with the exception of carbon. Accordingly, claim 10 has been cancelled. Applicants have further amended claim 7 to recite "treating the second section with an easily diffusable element." This treatment step is clearly not expressly or inherently taught in Yamauchi.

To establish the anticipation of a claim, the Examiner must show that each element of the claim at issue is found, either expressly or under the principles of inherency, in a single prior art reference. *Minnesota Mining & Mfg. Co. v. Johnson &*

Johnson Orthopaedics, Inc., 976 F.2d 1559, 24 U.S.P.Q.2d 1321 (Fed. Cir. 1992) (emphasis added). Further, "[t]he identical invention must be shown in as complete detail as is contained in the . . . claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989) (citations omitted). *See also* M.P.E.P. § 2131.

As stated, claim 7 now recites "treating the second section with an easily diffusable element." According to the specification, a section of a superelastic member can be treated by exposing it in a pressure chamber to an atmosphere enriched with one or more of the easily diffusable elements to alter its properties. *Id.*

As an initial matter, Yamauchi does not disclose treating a superelastic member in an elongated device with an easily diffusable element, and certainly not one selected from oxygen, nitrogen, and hydrogen, as claimed. Instead, Yamauchi discloses that at least the base part of a catheter guide wire consisting of a TiNi-type shape-memorizing alloy containing 0.25-5.0 at.% of carbon. See Yamamuchi, Abstract. For this reason alone, Yamauchi can not anticipate the claimed invention. To the extent that Yamamuchi discloses adding "0.25-5.0 at.% of carbon" to a TiNi alloy is irrelevant since carbon is not one of the "easily diffusable elements" claimed.

As Yamauchi does not teach each and every element of claims 7 and 22-26, Applicants submit that the §102(b) rejection of these claims is improper, and request that it be withdrawn.

B. The §102(e) rejection of claims 7, 10 and 22-26 in view of Anderson is improper

The Examiner has maintained the rejection of claims 7, 10 and 22-26 under §102(e) as allegedly anticipated by Anderson. Office Action, pages 2-3. Applicants disagree with and traverse this rejection for at least the following reasons.

Anderson discloses a guidewire (10) having an elongated proximal portion (12) including a distal end (13) and a distal portion (14). Anderson, column 2, lines 13-18 and 38-45. Distal end (13) is formed from a "substantially nickel-free high-nitrogen austenitic stainless steel alloy" (which is not superelastic). *Id.* Distal portion (14) is made from a "pseudo- or super-elastic [alloy]... such as nickel-titanium alloys." *Id.* In the alternative, Anderson discloses that both distal end (13) and distal portion (14) may be manufactured from stainless steel. *Id.* at lines 53-62.

The Examiner asserts that "Anderson... disclose[s] a superelastic member having a first section (14) with a first set of properties and an adjacent second section (12) having a second set of properties which have been altered from the first set of properties by alloying the second section with an easily diffusable element..." Office Action, page 2. Applicants respectfully disagree.

Contrary to the Examiner's assertion, Anderson does not alter the properties of a superelastic member in an elongated device by treating it with an easily diffusable element. The "substantially nickel-free high-nitrogen austenitic stainless steel alloy" used in Anderson "may be obtained from Carpenter Technology Corporations, Reading Pennsylvania as BioDur® 108." Anderson, col. 3, lines 11-15.

Furthermore, Anderson does not disclose an elongated device for medical procedures comprising, *inter alia*, "a superelastic member having a first section with a first set of properties and an adjacent second section with a second set of properties[,]" as recited in claim 7. That is, Anderson does not teach an elongated member having two adjacent superelastic sections, much less two adjacent superelastic portions wherein one portion exhibits altered properties as a result of being treated with an easily diffusable element selected from oxygen, nitrogen, and hydrogen, as claimed. Rather, as mentioned above, Anderson disclose a guidewire having a distal end (13) (first section) comprising austenitic stainless steel (which is not superelastic) and an adjacent distal portion (14) manufactured from either superelastic NiTi containing carbon *or* stainless steel. Anderson, column 2, lines 13-18, 38-45 and 53-62.

For at least the foregoing reasons, Anderson does not teach each and every element of pending claims 7 and 22-26. Therefore the rejection of these claims under 35 U.S.C. §102(e) as allegedly anticipated by Anderson is improper, and should be withdrawn.

C. The §103(a) rejection of claims 7, 10, 20, 21, 23 and 24 in view of Anderson and Stevens is improper.

The Examiner has also maintained the rejection of claims 7, 10, 20, 21, 23 and 24 under §103(a) as allegedly unpatentable over Anderson in view of Stevens. Office Action, pages 3-4. The rejection of claim 10 is moot in view of the above amendment. With respect to pending claims 7, 20, 21, 23 and 24, Applicants disagree with and traverse this rejection for at least the following reasons.

According to the Examiner, it would have been obvious to one of ordinary skill in the art at the time the invention was made to "modify the distal section as disclosed by Anderson et al. to include a nickel-titanium alloy which has been alloyed with an easily diffusable element as taught by Stevens et al. in order to allow the medical device to have a pre-formed shape, be stressed into another shape, and then return to its pre-formed shape" Office Action, pages 3-4. Applicants respectfully disagree for at least the following reasons.

In order to carry the initial burden of establishing a prima facie case of obviousness, the Examiner must show that the relied upon prior art references teach or suggest all of the elements of a claim. See M.P.E.P. § 2143. In addition, there must be some teaching or suggestion that would have motivated one of ordinary skill in the art to modify the references so as to arrive at the claimed invention. *See* M.P.E.P. § 2143.

First, neither Anderson nor Stevens discloses treating a superelastic member in an elongated device with an easily diffusable element selected from oxygen, nitrogen, and hydrogen, as claimed. Like Anderson, Stevens has obtained its alloy from a manufacturer. See Stevens, col. 3, lines 42-49.

Second, although Stevens disclose a NiTi alloy having other elements, Stevens does not correct Anderson's failure to teach an elongated member having two adjacent superelastic sections, much less two adjacent superelastic portions wherein one portion exhibits altered properties as a result of being treated with an easily diffusable element selected from oxygen, nitrogen, and hydrogen, as claimed. Thus, even if, *arguendo*, one of ordinary skill in the art would have been motivated to combine Anderson with

Stevens in the manner suggested by the Examiner, the resulting combination would still fail to teach or suggest each and every element of at least claim 7.

For these reasons alone, Applicants submit that the Examiner has failed to make a *prima facie* showing of obviousness. Several basic factual inquires must be made in order to determine whether the claims of a patent application are obvious under 35 U.S.C. § 103. These factual inquiries, set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), require the Examiner to:

> (1) Determine the scope and content of the prior art;
> (2) Ascertain the differences between the prior art and the claims in issue;
> (3) Resolve the level of ordinary skill in the pertinent art; and
> (4) Evaluate evidence of secondary considerations.

The obviousness or non-obviousness of the claimed invention is then evaluated in view of the results of these inquiries. *Graham*, 383 U.S. at 17-18, 148 USPQ 467; *see also KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727,1734 (2007); and M.P.E.P. § 2141.

Further, when making the determination of obviousness, the claimed invention and cited references must be considered as a whole, the references must be view without impermissible hindsight, and reasonable expectation of success is the standard with which obviousness is determined. *See Id.*; *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 (Fed. Cir. 1986). Finally, a showing of a teaching, suggestion, or motivation to combine the prior art references to meet the claimed subject matter could be helpful in determining whether the claimed subject matter is obvious under 35 U.S.C. § 103(a).

Thus, in order to satisfy the initial burden of establishing a *prima facie* case of obviousness, the Examiner first must show that the prior art references teach or suggest

all the claim limitations. *See In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). *See also* M.P.E.P. § 2143. The Examiner also must show that there is some suggestion or motivation, either in the references or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the references. *See In re Rouffet*, 149 F.3d 1350, 47 USPQ2d 1453 (Fed. Cir. 1998).

The Supreme Court, in the *KSR* decision, recognized that a showing of "teaching, suggestion, or motivation" could provide helpful insight in determining whether the claimed subject matter is obvious under Section 103(a). *KSR*, 127 S. Ct. at 1741.

In addition, the Supreme Court mandates that "[t]o facilitate review, this analysis [of whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue] should be made explicit." *Id.* (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness")).

Following the *KSR* decision, the Office issued a memorandum to its technology center directors on May 3, 2007, indicating that "in formulating a rejection under 35 U.S.C. § 103(a) based upon a combination of prior art elements, it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed." (Emphasis in original).

As shown, there is no teaching or suggestion in the cited references that would have motivated one of ordinary skill in the art to modify Anderson with Stevens in the

manner asserted. Admittedly, Stevens mentions alloying NiTi with various additional elements, including oxygen and hydrogen. However, neither Stevens nor Anderson, alone or in combination, provide any indication as to *why* NiTi treated with oxygen and/or hydrogen would be beneficially used in Anderson's guidewire. Indeed, neither Anderson nor Stevens provide any indication that NiTi alloyed with oxygen and/or hydrogen would function in an equivalent, much less superior degree to the alloys utilized in Anderson's guidewire.

Moreover, the motivation proposed by the Examiner - "in order to allow the medical device to have a pre-formed shape, be stressed into another shape, and then return to it original shape" - is ineffectual. Office Action, pages 3-4. *Any* superelastic NiTi alloy, if formed into a medical device, will allow the medical device to function in the manner asserted by the Examiner as motivation. That is, all superelastic NiTi alloys are capable of: a) having a pre-formed shape; b) being stressed into another shape; and c) returning to their original shape from the stressed shape. One of ordinary skill in the art would be aware of this fact, and therefore would not be motivated to substitute Stevens' alloy for the alloy utilized in Anderson based solely upon this proffered similarity.

For at least the foregoing reasons, Anderson and Stevens, alone or in combination, fail to teach or suggest each and every element of claims 7, 20, 21, 23 and 24 under §103(a) as being allegedly unpatentable over Anderson in view of Stevens is improper, and should be withdrawn.

III. Conclusion

In view of the foregoing remarks, Applicants submit that the claimed invention, as amended, is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicants therefore request the entry of this Amendment, the Examiner's reconsideration of the application, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

/Louis Troilo/

Dated: September 28, 2007 By:_____

Louis M. Troilo
Reg. No. 45,284